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June 15, 2021

VIA ECF

Special Master the Honorable Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, PA 19103

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Special Master Vanaskie:

On behalf of the Defense Executive Committee, this letter is to provide Defendants' positions with respect to the topics on the agenda for the Zoom meeting with Your Honor on June 16, 2021.

1. Humana's Proposed Motion

Humana, a third-party payor, filed its initial economic loss complaint against certain defendants on August 7, 2020, alleging claims mirroring those brought by other third party payors in the master economic loss complaint. On December 17, 2020, Humana filed a motion for leave to amend its complaint to add additional defendants. The Court granted this motion on December 18, 2020, and Humana filed its amended complaint on the same day. On January 27, 2021, Humana filed a further second amended complaint, again mirroring the claims brought by other third party payors.

On April 6, 2021, Humana asked defendants named in its January 2021 complaint to stipulate to a stay of Humana's case "pending resolution of the class certification motion."



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Humana's position, as explained to defendants, was that the case should be stayed in order to avoid "'satellite litigation' during the pendency of the class certification proceedings and in light of the fact that Humana is a putative member of the class that TPPs will seek to certify."

As Defendants informed Humana, Defendants cannot agree to a stay of Humana's case for numerous reasons, and Humana must litigate the case it filed against Defendants. In response, Humana then asked whether Defendants would be willing to stipulate that Humana is a member of the third-party payor class. As Defendants explained to Humana, although Defendants would consider whatever stipulation Humana may send on this issue, Defendants do not have the ability to define the putative class membership, and that issue is something Humana needed to address with other Plaintiffs' counsel. Humana indicated that it would discuss further with its client, and Defendants have not heard anything further from Humana. Defendants do not believe any potential dispute with Humana is ripe for resolution at this time as there are currently no motions pending.

2. Hetero Discovery and Privilege Log Update

Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (collectively, "HLL") is continuing to work cooperatively with Plaintiffs to address their specific discovery demands that remain following several meet and conferrals and document productions.

During our last Case Management Conference on June 3, 2021, Your Honor directed HLL to produce the remaining documents responsive to Plaintiffs' document requests by June 7, 2021. Specifically, Plaintiffs requested "Derek Reports" regarding genotoxic analysis conducted by HLL as well as documents related to the development of HLL's Process III for Valsartan. Derek is a commercially available program utilized in the manufacturing process to determine potential



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toxicity risks of the combination of chemicals used therein. Accordingly, on June 7, 2021, HLL produced all Derek Reports related to Valsartan as well as the Development Report for Valsartan Process III.

Thereafter, on June 10, 2021, Plaintiffs transmitted a discovery deficiency letter to HLL. Several categories of documents requested in Plaintiffs' June 10 letter were already produced by HLL, so on June 14, 2021, HLL provided a spreadsheet setting forth the precise bates ranges for several categories of documents contained in Plaintiffs' June 10 letter. Plaintiffs' letter further requested specific chromatograms that Plaintiffs were unable to locate in HLL's document productions. HLL conferred with the third-party laboratory that conducted the testing, located and retrieved the chromatograms requested, and made a supplemental document production to Plaintiffs today, June 15, 2021, containing relevant chromatograms that Plaintiffs stated were not present in HLL's prior document productions.

On June 14, 2021, the parties met and conferred by telephone regarding Plaintiffs' June 10 letter. There, Plaintiffs explained the additional information regarding the development of Process III, other than that contained in the Development Report for Valsartan Process III, that Plaintiffs request. In light of this information, HLL informed Plaintiffs that we will confer with our client regarding whether there are any additional responsive documents, or alternatively, an HLL 30(b)(6) witness will testify during their upcoming deposition regarding the unavailability of additional responsive documents. We have informed Plaintiffs that we will follow up on that determination upon conferral with our client.

Further, the parties discussed the input and output data contained in the Empower software, which HLL utilized to conduct non-nitrosamine related chromatography testing of its



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manufactured batches of Valsartan. The parties discussed the difficulty in transmitting a usable version of the raw input data, which requires credentials to access within the software, and agreed to continue to meet and confer on the best method to transmit that input data. Plaintiffs' Counsel acknowledged that it was continuing to investigate the format required for this raw data, and we are awaiting that information in order to complete the production. As of the parties' meet and confer on June 14, Plaintiffs had not yet determined the preferred format for that production. As to the output data, which is in the form of chromatograms, HLL informed Plaintiffs that we are conferring with our client regarding retrieval of those non-nitrosamine related chromatograms.

Finally, during the meet and conferral Plaintiffs additionally raised discreet issues regarding specific documents that they were unable to locate in our document productions. Plaintiffs categorized these outstanding documents as "general housekeeping" and thus not of high priority. We informed Plaintiffs that we would locate the bates ranges of the remaining documents, or alternatively produce the documents forthwith.

Accordingly, HLL is continuing to work in good faith to resolve many of the issues raised by Plaintiffs and is continuing to work with Plaintiffs in productive meet and conferrals regarding any documents that remain.

3. Plaintiffs' Motion to Compel the Production of ZHP President Baohua Chen's Custodial File and the ZHP Parties' Cross-Motion for a Protective Order

Plaintiffs' motion to compel the production of ZHP President Baohua Chen's custodial file and the ZHP Parties' cross-motion for a protective order has been fully briefed and is *sub judice*.



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4. The ZHP Parties' Motion for Protective Order Precluding the Deposition of ZHP President Baohua Chen Under the Apex Deposition Doctrine

The ZHP Parties' motion for a protective order precluding the deposition of ZHP President Baohua Chen under the apex deposition doctrine has been fully briefed and is *sub judice*.

5. ZHP's Supplemental Production of Documents

The ZHP Parties substantially completed the production of documents responsive to Plaintiffs' new discovery requests on June 11, 2021, and are in the process of performing quality checks of the latest collection and production. Due to a shortage in China of the hardware needed to collect the custodial file of Maggie Kong, her custodial file has not yet been collected and analyzed for potentially privileged documents, as the Court had previously advised the ZHP Parties. The ZHP Parties are diligently working to secure the hardware needed, and will continue to update the Court of the status of Ms. Kong's collection.

6. Hearing Regarding Meridan and ToxRox (Special Master Order No. 22)

On June 11, 2021, the Aurobindo parties withdrew their Motion for Protective Order Regarding Plaintiffs' Third Party Subpoenas directed to Meridan Consulting and ToxRox Consulting, LLC. The documents subject to the subpoenas were produced to Plaintiffs' counsel on June 14, 2021.

Thank you for your consideration, and we look forward to speaking with Your Honor on these issues.

Respectfully submitted,

/s/ Lori G. Cohen

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cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
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